PATENT CLAIMS

1. A pharmaceutical composition containing platinum complex of formula (I) as an active substance

$$A \xrightarrow{Pt} X$$

$$X'$$

$$X'$$

$$X'$$

where

A and A', independently of each other, are NH<sub>3</sub> group or amine or diamine group containing 1 to 18 carbon atoms,

B and B', independently of each other, are halogen atom, hydroxyl group or COOR or COOR' group where R and R', independently of each other, are hydrogen atom or alkyl, alkenyl, aryl, aralkyl, alkyl amine or alkoxyl group containing 1 to 10 carbon atoms or functional derivatives of the said groups, and

X and X', independently of each other, are halogen atom or monocarboxylate group containing 1 to 20 carbon atoms, or

X and X' together form dicarboxylate group containing 2 to 20 carbon atoms, in a mixture with at least one pharmaceutically acceptable excipient characterized in that it is formed of a granulate with particles smaller than 0.5 mm in size prepared by wet granulation of a mixture of platinum complex of tetravalent platinum of formula (I) wetted by water, at least one neutral saccharide and at least one native and/or modified polysaccharide.

- 2. The pharmaceutical composition according to Claim 1 characterized in that it is formed of the granulate prepared by wet granulation of the mixture of platinum complex of formula (I), at least one neutral saccharide at an amount equal to at least 5 % by weight and at least one native and/or modified polysaccharide at an amount equal to at least 2 % by weight, related always to the total weight of the granulate.
- 3. The pharmaceutical composition according to Claim 1 or Claim 2 characterized in that it contains at least one pharmaceutically acceptable releasing agent and/or at least one pharmaceutically acceptable slipping substance.

- 4. The pharmaceutical composition according to one of Claims 1 to 3 characterized in that it contains (OC-6-43)-bis(acetato)-(1-adamantylamine)-amine-dichloroplatinic complex as the active substance.
- 5. The pharmaceutical composition according to one of Claims 1 to 4 characterized in that the mixture intended for wet granulation contains lactose, mannitol, sorbitol, fructose, glucose and/or saccharose as the neutral saccharide.
- 6. The pharmaceutical composition according to one of Claims 1 to 5 characterized in that the mixture intended for wet granulation contains maize, wheat and/or potato starch as the native and/or modified polysaccharide.
- 7. The pharmaceutical composition according to one of Claims 1 to 6 characterized in that it is contained in a capsule or a sack or is pressed into a tablet form.
- 8. The pharmaceutical composition according to one of Claims 1 to 7 characterized in that the surface of the granulate, the capsule or the tablet is coated with a layer of at least one pharmaceutically acceptable substance enabling enterosolvent dissolution of the active substance in bowels only, and/or with a layer of at least one pharmaceutically acceptable substance enabling controlled release of the active substance.
- 9. The pharmaceutical composition according to Claim 8 characterized in that the surface of the granulate or the tablet is separated from the layer of at least one pharmaceutically acceptable substance enabling enterosolvent dissolution of the active substance in bowels only and/or from the layer of at least one pharmaceutically acceptable substance enabling the controlled release of the active substance with an inert closing layer consisting of at least one neutral saccharide, for example saccharose, and/or with at least one native and/or modified polysaccharide, for example native or modified maize, wheat or potato starch or gelatine or gum arabic, while the weight of the inert closing layer does not exceed 15% by weight, related to the total weight of the granulate or the tablet.
- 10. The pharmaceutical composition according to Claim 8 or Claim 9 characterized in that the layer of at least one pharmaceutically acceptable substance enabling the controlled release of the active substance is formed of ethyl cellulose and/or methacrylic acid and/or its compounds, advantageously polymers and/or copolymers of methacrylic acid, while the weight of the said layer is equal to not more than 40% by weight, related to the weight of the granulate, the capsule or the tablet.

- 11. The pharmaceutical composition according to one of Claims 8 to 10 characterized in that the layer of at least one pharmaceutically acceptable substance enabling enterosolvent dissolution of the active substance in bowels only is formed of cellulose acetate and/or cellulose acetate and/or cellulose acetyl phthalate and/or cellulose acetosuccinate and/or hydroxypropylmethylcellulose phthalate and/or hydroxypropylmethylcellulose succinate and/or polyvinyl alcohol phthalate and/or benzophenyl salicylate and/or styrene copolymer with maleic acid and/or shellac and/or methacrylic acid and/or its compounds, advantageously polymers or copolymers of methacrylic acid while the weight of the said layer is equal to not more than 15% by weight, related to the weight of the granulate, the capsule or the tablet.
- 12. A method of manufacturing of the pharmaceutical composition according to one of Claims 1 to 11 characterized in that the mixture of platinum complex of formula (I) wetted by water, at least one neutral saccharide and at least one native and/or modified polysaccharide is granulated under wet conditions to obtain granulate consisting of particles smaller than 0.5 mm in size.
- 13. The method according to Claim 12 characterized in that the wet granulation is performed to obtain granulate having such distribution of sizes of particles that 90% of them are smaller than 2.0 mm in size and not more than 20% of the particles are smaller than 0.09 mm in size.
- 14. The method according to Claim 12 or Claim 13 characterized in that the wet granulation is performed in equipment, the surfaces of which, coming into contact with the granulated mixture are inert to said mixture.
- 15. The method according to one of Claims 12 to 14 characterized in that the granulate is filled into a capsule or a sack or, after at least one releasing agent and/or at least one slipping agent is added to the granulate, pressed into tablets.
- 16. The method according to Claim 15 characterized in that filling into capsules and sacks and tablet-making is performed in equipment, the surfaces of which, coming into contact with the mixture filled into capsules or sacks or with the mixture intended for tablet-making are inert to said mixture.
- 17. The method according to one of Claims 12 to 16 characterized in that the granulate surface, the surface of the granulate to be filled into the sack, the tablet surface and the surface of the granulate to be filled into the capsule and/or the surface of the capsule mentioned are coated with a layer of at least one pharmaceutically acceptable substance

enabling enterosolvent dissolution of the active substance in bowels only and/or a layer of at least one pharmaceutically acceptable substance enabling the controlled release of the active substance.

- 18. The method according to Claim 17 characterized in that the granulate surface, the surface of the granulate to be filled into the sack, the surface of the granulate to be filled into the capsule and the surface of a tablet, before being coated with the layer of at least one pharmaceutically acceptable substance enabling enterosolvent dissolution of the active substance in bowels only and/or the layer of at least one pharmaceutically acceptable substance enabling the controlled release of the active substance, are provided with an inert closing layer formed of at least one neutral saccharide, for example saccharose, and/or at least one native and/or modified polysaccharide, for example native or modified maize, wheat or potato starch or gelatine or gum arabic.
- 19. The method according to Claim 17 or Claim 18 characterized in that coating of the granulate and the tablets with the inert closing layer, the layer of at least one pharmaceutically acceptable substance enabling enterosolvent dissolution of the active substance in bowels only or the layer of at least one pharmaceutically acceptable substance enabling the controlled release of the active substance is performed in equipment, the surfaces of which, coming into contact with the granulate or the tablets are previously coated with a material forming the inert closing layer.